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Filed : October 20, 2003

### REMARKS

Claim 1 has been amended to clarify the claimed invention. Claims 6-10 have been added. Support for amended claim 1 and added claims 6-10 can be found in the Specification and claims as filed, for example, Figure 24 and pages 30, line 14 through page 31, line 5. The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

As requested in the Office Action, the Priority information has been amended to reflect the issued patent and the Summary of the Invention has been amended to reflect the elected claim set. A copy of the IDS of January 25, 2004 is enclosed containing the patent GB 1,335,290 which was not received by the Examiner.

#### Rejection under 35 U.S.C. §102(b)

Claim 1 stands rejected as anticipated by Armbruster et al (USPN 5,322,511). The Office Action states that Armbruster discloses an injector with a syringe barrel (80) having a flange (92) and a concave portion (94,96,96' or 94,98, 98') in Figures 11-12. Figure 10 shows a slot 72 for the insertion of the flange therein. Figure 16 shows the guide engaging a portion (74) of the cylinder holder. The Examiner believes that this "lock and key" mechanism restricts the mounting direction of the syringe barrel.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Claim 1 is directed to a cylinder holder for an injection apparatus adopted for holding a syringe barrel, having a flange insertion groove to fix the syringe barrel by holding a flange on the syringe barrel; and a positioning mechanism installed in the cylinder holder and adapted to engage a concave portion on the syringe barrel. The claim has been amended to specify that the

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positioning mechanism engages the concave portion on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to a use position. Embodiments of the positioning mechanism on the cylinder holder are the blade spring shown in Figure 24 and described in pages 30, line 14 through page 31, line 5 of the specification and the coil spring shown in Figures 22 and 23 and described in page 28, lines 13 through 16. In these cases, the syringe can be rotated to a locked "use" position in which the positioning mechanism is inserted into the concavity on the syringe.

In Figure 16 of Armbruster there is disclosed a positioning mechanism 74 which allows for the directional insertion of the syringe. Rotation of the syringe barrel is impossible because the positioning mechanism is fixed and not movable and also because the flange is diamond shaped.

Thus, Armbruster does not anticipate the claims because Armbruster does not teach a positioning mechanism that engages the concave portion on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to a use position.

#### **Rejection under 35 U.S.C. §103(a)**

Claims 1 and 3-5 stand rejected as unpatentable over Reilly et al (USPN 4,677,980) (hereinafter Reilly) in view of Fago et al (USPN 6,569,127), (hereinafter Fago). Claim 2 is rejected as unpatentable over Reilly et al in view of Fago et al. and further in view of Rait (USPN 5,429,611) (hereinafter Rait) The Examiner believes that Reilly meets all of the claim limitations for Claims 1 and 2, except for the cylinder holder having an insertion groove. The Office Action further asserts that Fago discloses a groove/flange attachment system. Further, with respect to Claim 2, the Office Action indicates that Rait discloses a positioning mechanism being a blade spring with a pawl or latch, but fails to teach that the blade spring could be a coil spring.

The law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

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Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1440 (Fed. Cir. 1991)).

**Claims 1 and 3-5** are directed to a cylinder holder having a positioning mechanism to engage a concave portion, provided on the syringe barrel. The claim has been amended to specify that the positioning mechanism engages the concave portion on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to the use position. Embodiments of the positioning mechanism are the blade spring shown in Figure 24 and pages 30, line 14 through page 31, line 5 and the coil spring shown in Figures 22 and 23 and page 28, line 13 through 16. In each case, the syringe can be rotated to the locked position in which the coil spring or the blade spring is inserted into the concavity on the syringe. This is the "use" position.

Applicants respectfully submit that the Office Action is not correct in its characterization of Reilly. The Office Action states that the positioning mechanism (126) of Reilly is adapted to engage a concave portion (133) provided on the syringe barrel (18). In fact, the concave portion (133) is provided on a pressure jacket 16', see column 8, lines 55-66. The syringe barrel 18 is housed in the pressure jacket. What is seen outside on Figure 1 is the pressure jacket 16, not the syringe barrel. Thus, Reilly does not disclose a positioning mechanism on the cylinder holder adapted to engage a concave portion provided on the syringe barrel.

Fago does not provide the missing claim elements, because Fago does not disclose a positioning mechanism on the cylinder holder adapted to engage a concave portion provided on the syringe barrel.

Thus, the combination of Reilly and Fago does not render Claims 1 and 3-5 obvious because it does not include all of the claim elements. The combination does not include a positioning mechanism on the cylinder holder adapted to engage a concave portion provided on the syringe barrel. Further, even if the combination did teach that aspect of the invention, they do not teach that the positioning mechanism engages the concave portion on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to the use position.

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Thus, the combination of Reilly in view of Fago does not render Claims 1 and 3-5 obvious because the combination does not teach all of the claim elements.

With respect to Claim 2, the Office Action further asserts that Reit teaches a syringe with a pivotable latches/pawls (20) that are biased by a coiled spring (28) in Figures 1 and 3. However, Claim 2 is dependent upon Claim 1, and, as stated above, the combination of Reilly and Fago do not teach all of the claim elements because they do not teach a positioning mechanism installed in the cylinder holder which engages a concave portion provided on the syringe barrel. Further, even if they did teach that aspect of the invention, they do not teach that the positioning mechanism engages the concave portion on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to the use position.

Reit teaches that both the concavity and a coiled spring are on the cylinder holder. Thus, Reit does not provide the missing claim elements and the combination of Reilly, Fago, and Reit do not render Claim 2 obvious.

#### **New Claims 6-10**

Applicants would like the Examiner to note that Claims 6-10 are not anticipated nor obvious in view of Armbruster, Reilly and Fago alone or in combination because the new claims recite that "the flange on the syringe barrel is capable of being inserted into the flange insertion groove in the state that the syringe barrel and a syringe is coupled, wherein said syringe piston has a rod and wherein said syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves." In contrast, all of the cited references disclose rod-less type syringes and all use front-load type injectors.

#### **Conclusion**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone

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number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated:

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